Best® medical international

K132097

Attachment 5 (Page 1)

510(k) Summary

Summary of Safety and Effectiveness:

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the proposed Best Medical International, "Best® Multi-Lumen Balloon Applicator for Brachytherapy "

Manufacturer: Best Medical International, Inc.
7643 Fullerton Road
Springfield, VA 22153
Phone: (703) 451-2378
Fax: (703) 451-4736.

SEP 3 0 2013

Contact Person: Dharmendra Thakur
Manager, Quality and Regulatory Affairs
Phone: (703) 451-2378 Ext 162
Mobile: 703-303-8030
Fax: (703) 451-4736.

Device Name:

Trade Name: "Best® Multi-Lumen Balloon Applicator for Brachytherapy "

Common Name: Multi Lumen Balloon Source Applicator

Proprietary name: "Best® Multi-Lumen Balloon Applicator for Brachytherapy "

Classification: 21 CFR 892.5700

Date Prepared: July 05, 2013

Predicate Device: Contura Multi-Lumen Balloon Source Applicator for Brachytherapy

Predicate Device 510(k): K081079

Trade/ Device Name: "Best® Multi-Lumen Balloon Applicator for Brachytherapy "

Regulation Number: 21 CFR 892.5700

Regulatory Class: II

Product code : JAQ

Device Description :

The Best® device is a multi-catheter brachytherapy device consisting of an inflatable outer spherical balloon and an inner inflatable balloon for treatment catheter positioning. Each catheter can be attachment to a commercially available High Dose Rate remote afterloader for passage of the source wire and radiation source into each of the catheter lumens. Five treatment lumens are provided, one central lumen located along the long axis of the applicator and four moveable lumens, which are symmetrically offset from the central lumen by inflation of an inner balloon, which positions the treatment lumens at a location greater than or equal to 50% of the outer balloon diameter. A removable stiffening stylet is positioned in the central treatment lumen for initial placement into the resection cavity, as well for repositioning of the device as needed. Three proximal ports are also provided with Luer-locktype connectors for inner and outer balloon inflation/deflation and for application of intracavitary vacuum for removal of air and/or fluid.

Intended Use:

"Best® Multi-Lumen Balloon Applicator for Brachytherapy" is intended to provide brachytherapy when the physician chooses to utilize a High Dose Rate remote afterloader device to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

Indications for Use:

"Best® Multi-Lumen Balloon Applicator for Brachytherapy" is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer. It is supplied as a single-use sterile device. The device is indicated for use under the direct supervision of a qualified physician.

Comparison of Technological Characteristics: "Best® Multi-Lumen Balloon Applicator for Brachytherapy" shares many structural and functional features with the FDA-approved Contura®Multi-lumen Balloon Brachytherapy Device. Both are catheter devices that are intended to deliver radiation to the surgical margins following lumpectomy for breast cancer and both use an inflatable balloon to conform radiation delivery based on the shape and size of the tumor being treated. They have similar design characteristics; same operating principle and similar technological characteristics. Therefore, it can be concluded that the proposed device is substantially equivalent to the predicate device.

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A Comparison with Predicate Device is shown in table below:

	The Best® Device	Predicate Device
Device	"Best® Multi-Lumen Balloon Applicator for Brachytherapy"	Contura® Multi-lumen Balloon Source Applicator for Brachytherapy –**K081079**
Device Description	The Best® Multi-Lumen Balloon Applicator for Brachytherapy consists of a multi-lumen catheter attached to an inflatable inner and outer spherical balloon. Lumens are provided for attachment to a commercially available High Dose Rate remote afterloader for passage of the radiation treatment delivery wire and source. Five treatment lumens are provided, one central lumen located along the long axis of the applicator and four lumens which are symmetrically offset from the central lumen by inflation of an inner balloon which positions the treatment lumens at greater than or equal to 50% of the outer balloon diameter. A removable stiffening stylet is located in the central treatment lumen. Three proximal ports are also provided with Luer-type connectors for inner and outer balloon inflation/deflation and for application of intracavitary vacuum.	The Contura® Multi-lumen Balloon Source Applicator for Brachytherapy consists of a multi-lumen catheter attached to an inflatable spherical balloon. Lumens are provided for attachment to a commercially available High Dose Rate remote afterloader for passage of the radiation treatment delivery wire. Five treatment lumens are provided, one central lumen located along the long axis of the applicator and four curved lumens symmetrically offset from the central lumen by approximately 5 mm on a fixed plastic mount. A removable stiffening stylet is located in the central treatment lumen. Two proximal ports are also provided with Luer-type connectors for balloon inflation/deflation and for application of intracavitary vacuum.
Intended Use	"Best® Multi-Lumen Balloon Applicator for Brachytherapy" is intended to provide brachytherapy when the physician chooses to utilize a High Dose Rate remote afterloader device to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.	The Contura® Multi-Lumen Balloon is intended to provide brachytherapy when the physician chooses to utilize a High Dose Rate remote afterloader device to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

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Indications for Use:	"Best® Multi-Lumen Balloon Applicator for Brachytherapy" is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer. It is supplied as a single-use sterile device. The device is indicated for use under the direct supervision of a qualified physician.	The Contura® Multi-Lumen Balloon Source Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

Conclusion: Performance tests were conducted to evaluate and characterize the performance of the "Best® Multi-Lumen Balloon Applicator for Brachytherapy". These tests included dimensional comparisons of the inflated outer balloon at various volumes, HDR source transition in and out of the treatment catheters on an inflated inner balloon, and CT image quality. The "Best® Multi-Lumen Balloon Applicator for Brachytherapy" performed as intended.

The proposed device is substantially equivalent to the approved Contura®Multi-lumen Balloon Source Applicator for Brachytherapy and is as safe and effective as the approved device. Upon reviewing and comparing the proposed device and predicate device, the classification, the intended use, indication for use, method of use and technological characteristics, it can be concluded that the proposed device (The "Best® Multi-Lumen Balloon Applicator for Brachytherapy" is substantially equivalent to the Predicate device (Contura®Multi-lumen Balloon Source Applicator for Brachytherapy – 510(K)# K081079).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 30, 2013

Best Medical International, Inc.
% Mr. Dharmendra Thakur
Manager, Quality and Regulatory Affairs
7643 Fullerton Road
SPRINGFIELD VA 22153

Re: K132097
Trade/Device Name: Best® Multi-Lumen Balloon Applicator for Brachytherapy
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ
Dated: July 5, 2013
Received: July 17, 2013

Dear Mr. Thakur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

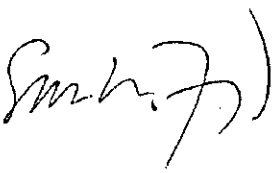
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Attachment 4

Indications for Use Form

510(k) Number (if known): K132097

Device Name: **"Best® Multi-Lumen Balloon Applicator For Brachytherapy "**

Indications for Use:

Best® Multi-Lumen Balloon Applicator for Brachytherapy is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer. It is supplied as a single-use sterile device. The device is indicated for use under the direct supervision of a qualified physician.

The safety and effectiveness of The Best Multi-Lumen Balloon Applicator for Brachytherapy as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

Prescription Use _X_____ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Division Sign-Off
Office of In Vitro Devices and Radiologic Health
Division of Radiological Health (DRH)

510(k) K132097